

### **REMARKS**

Claims 11, 13-14, 18-20, 33-41, 44, 50-55, 57-58, and 60 are pending in the present application. In view of the following, further and favorable consideration is respectfully requested.

***I. At page 3 of the Official Action, claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58, and 60 have been rejected under 35 USC § 112, first paragraph.***

The Examiner asserts that the specification, “particularly at Example 12, while being enabling for pantoprazole sodium sesquihydrate does not reasonably provide enablement and support for the group of active agents presented in instant claim 11.” On page 4 of the Official Action, the Examiner further applies the rejection asserting that while Example 12 is enabling for solidified drops, it is not enabling for a “microsphere,” as recited in the present claims.

Applicants respectfully traverse the rejection of claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58, and 60.

The enablement provision of the Patent Act requires that the patentee provide a written description of the invention “in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.” 35 U.S.C. § 112, first paragraph (2000). The purpose of this requirement is to ensure that “the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.” *Nat’l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195-96 (Fed. Cir. 1999); See also Donald S. Chisum, 3 *Chisum on Patents* § 7.01 (2002).

Accordingly, the specification must provide sufficient teaching such that one skilled in the art could make and use the full scope of the invention without undue experimentation. *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003); *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997); *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988). "The key word is 'undue,' not experimentation." *Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Routine experimentation does not constitute undue experimentation. See *Johns Hopkins University v. Cellpro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998). That is, the specification need only teach those aspects of the invention that one skilled in the art could not figure out without undue experimentation. See, e.g., *Nat'l Recovery Techs.*, 166 F.3d at 1196 ("The scope of enablement . . . is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation."); *Wands*, 858 F.2d at 736-37 ("Enablement is not precluded by the necessity for some experimentation such as routine screening."). "Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." See *In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993).

Although the ultimate determination of whether one skilled in the art could make and use the claimed invention without undue experimentation is a legal one, it is based on underlying findings of fact. *CFMT*, 349 F.3d at 1337. Furthermore, "[w]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Wands*, 858 F.2d at 737.

Some of these considerations, commonly referred to as “the *Wands* factors,” include “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *Id.*; see also *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991) (stating that the *Wands* factors “are illustrative, not mandatory” and that what is relevant to an enablement determination depends upon the facts of the particular case).

With regard to the presently pending claims, Applicants respectfully submit that the specification, figures, and experimental examples provide ample guidance to the skilled artisan in view of the state of the art, at the time the application was filed, to make and use the claimed invention without undue experimentation.

Additionally, Applicants respectfully submit that the court in *In re Wright* held that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples.

When discussing the present claims, the Examiner refers to only Example 12 of the present specification. Applicants note that Example 12 was previously cited by Applicants merely to show one of many places in the specification which provides enablement and support for the full scope of the present claims. Limiting the scope of the present claims to a single Example is simply improper. Accordingly, US case law is very clear that **a *specification need not contain even***

**one working example** if the subject matter is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation. See *In re Long*, 368 F.2d 892, 151 USPQ 640 (C.C.P.A. 1966), *In re Borokowski and Van Venrooy*, 422 F.2d 904, 164 USPQ 642 (C.C.P.A. 1970).

As such, **a finding of lack of enablement must be based on the disclosure of the specification as a whole and the level of skill in the art**, and not merely on the Examples.

Accordingly, should the Examiner maintain this rejection, Applicants respectfully request, in accordance with the principles of compact prosecution, that the Examiner address, on the record and with specificity sufficient to support a *prima facie* case of non-enablement, the factual basis on which it is alleged that a person having ordinary skill in the art would not be able to take the generic and specific teachings of the present specification to make and use the full scope of the claims in view of both the teachings in the specification and what was known to those skilled in the art. (MPEP § 2416.01)

Additionally, Applicants request that should the Examiner have any further rejections to be made regarding presently claimed terms or phrases, the Examiner make any and all such rejections in the next Official Action issued. In this regard, Applicants respectfully note that the term “microsphere” discussed by the Examiner in the present action was originally presented in the original claims filed almost eight (8) years ago. The Examiner is reminded that under MPEP § 707.07(g), piecemeal examination should be avoided as much as possible, and the Examiner should reject each claim on all valid grounds available in a first Official Action on the merits.

In contrast the term “microsphere” in the presently pending claims has been present in the claims since they were originally filed on December 4, 2001, but was never rejected as lacking enablement until this, the **tenth** Official Action on the merits. As the USPTO itself has explained, “[t]he Office’s policy of compact prosecution requires that both examiners and applicants provide the information necessary to raise and resolve the issues related to patentability expeditiously.” See the Official Gazette of 07 November 2003. Accordingly, the Examiner is officially requested to comply with the principle of compact prosecution and, should another Action be issued, actually include all potential rejections.

Applicants note that without the teachings in the present specification a skilled artisan would not have been able to make or use the presently claimed subject matter; however, with both the level of skill in the art, and the generic and specific teachings in the present specification, a skilled artisan would surely be able to make and use the presently claimed subject matter, specifically the group of active agents and microsphere recited in the present claim, without undue experimentation.

With regard to the microspheres, the Examiner asserts that statement that “[t]he term ‘microsphere’ connotates a specific size limitation not envisioned by the words [sic] ‘solids’ as recited in the working examples.” See the Official Action at page 4. In view of the Examiner’s lack of analysis in this rejection, Applicants submit that it is unclear what the Examiner really means by this statement. However, it appears that the Examiner is asserting that since a specific size is not recited in the Examples, it is unclear how a person of ordinary skill in the art would

know that "microspheres" are actually being prepared.

Applicants respectfully direct the Examiner's attention to the sentence directly after Example 15, which appears on page 16 of the present specification. That sentence states that "[t]he preparations obtained according to Examples 1-15 have a particle size in the range of 50-700 $\mu$ m." A person of ordinary skill in the art would recognize that the range of 50-700 $\mu$ m falls within the range given on page 9 of the disclosure – 3<sup>rd</sup> full sentence from the bottom of the page – wherein it states: "...the individual active compound units can be obtained in the form of microspheres having a narrow monomodal particle spectrum in the particle size range from 50  $\mu$ m to 2 mm." Also, Applicants respectfully direct the Examiner's attention to page 10 of the present specification wherein it states that "[t]he microspheres are preferably monomodal microspheres having a particle size range of 50-800 $\mu$ m...." Applicants remind the Examiner, that the aforementioned passages may not be considered to be exhaustive of the specification or the knowledge of skill in the art. However, Applicants submit that taken in view of the level of skill in the art, the specification is clearly enabling for the claimed microsphere.

Therefore, Applicants respectfully submit that the presently pending subject claims are fully compliant with 35 USC § 112, first paragraph. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

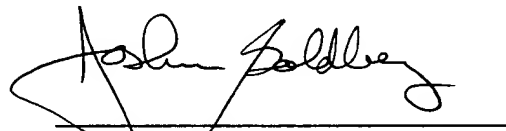
***Conclusion***

In view of the foregoing, applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Gary M. Nath", is written over a horizontal line.

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